

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/23634

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 31/00; G01N 33/53; 33/543

US CL : 73/64.47; 424/449; 435/3; 436/807; 514/1

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 73/64.47; 424/449; 435/3; 436/807; 514/1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
Please See Continuation Sheet

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	WO 02/16941 A2 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA) 28 February 2002, see entire document.	1-8, 13-18, 33, 35-41, 44-46, 52 ----- 9-12, 19-32, 34, 43, 47-51
Y	WO 02/06518 A1 (TRANSFORM PHARMACEUTICALS, INC.) 24 January 2002, see entire document	9-12, 19-32, 34, 43, 47-51
Y	VIAN, L. et al., "Comparison of Three In Vitro Cytotoxicity Assays for Estimating Surfactant Ocular irritation", Toxic. In Vitro, Vol. 9, No. 2 pages 185-190 (1995), see entire article.	19-32, 34, 43, 47-51
Y	FDA: "Guidance for Industry: Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products" Internet at: <a href="http://www.fda.gov/cder/guidance/index.htm">http://www.fda.gov/cder/guidance/index.htm</a> , (updated 3/8/01) pages 1-8, see entire document.	19-32, 34, 43, 47-51



Further documents are listed in the continuation of Box C.



See patent family annex.

\* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

08 December 2004 (08.12.2004)

Date of mailing of the international search report

28 JAN 2005

Name and mailing address of the ISA/US

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## C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---	US 5,446,025 A (LU et al.) 29 August 1995, see entire document.	32, 35-41, 44-50, 52
Y		32
X	US 5,947,921 A (JOHNSON et al.) 7 September 1999, see entire document.	33, 35-41, 44-50, 52
X	Pharmaceutical Skin Penetration Enhancement: MOLLGAARD, B "Synergistic Effects in Percutaneous Enhancement", (ed.: K. Walters & J. Hadgraft 1993), New York, Marcel Dekker pages 229-242, see entire article.	33, 35-41, 44-48, 50, 52
A	US 5,490,415 A (MAK et al.) 13 February 1996, see entire patent.	1-52
A	KARANDE, P et al., Pharm. Res. Vol. 19, No. 5 (May 2002) pages 655-660, see entire article.	1-52
A	SANTUS, G.C. et al., "Transdermal Enhancer Patent Literature", J. Controlled Release Vol. 25 (1993) pages 1-20, see entire article.	1-52
A	MITRAGOTRI, S "Synergistic Effect of Enhancers for Transdermal Drug Delivery", Pharm. Res. Vol. 17, No. 11 (2000) pages 1354-1359, see entire article.	1-52

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## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:  
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐  
☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

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## BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Gp 1: claims 1-32, 34 and 51 drawn to screening methods.

Gp. 2: claims 33, 36-41 and 45-46 drawn to enhancer compositions.

Gp. 3: claims 35, 44, 47-50 and 52 drawn to bioactive containing compositions & use.

Gp. 4: claim 42 drawn to composition comprising lauryl ether sulfate & 1-phenyl piperazine.

Gp. 5: claim 43: drawn to composition comprising lauryl sarcosine & sorbitan monolaurate.

The above groups lack unity since their shared features are not "special" technical features. Diffusion (e.g. membrane) apparatus and screening method of penetration enhancers are known in the art (see e.g. WO 02/16941) as are synergistic penetration enhancer compositions for transdermal delivery (e.g. see US 5,446,025 and US 5,947,921 documents).

Continuation of B. FIELDS SEARCHED Item 3:

WEST: USPT, PGPB, USOC, EPAB, JPAP, DWPI, TBD.

STN: FILE REG, CAPLUS, EMBASE, BIOSIS, MEDLINE, WPIDS, DRUGU, CHEMINFORMEX, USPATFUL.